

On-Site Laboratory Evaluation Report (SDWA)

Date of Report: October 21, 2009

Microbiology

**Environmental Microbiology Section
Office of Laboratory Services
Bureau for Public Health
West Virginia Department of Health and Human Services
167 11th Avenue
South Charleston, WV 25303**

Date of Assessment: September 22-23, 2009

by

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A. Introduction:

On September 22-23, 2009, an evaluation of the Environmental Microbiology Laboratory of the West Virginia Office of Laboratory Services, located in Charleston, was conducted to determine the capability of the Laboratory to perform its mission as it relates to the Safe Drinking Water Act. The Laboratory was last evaluated in September, 2006.

The Environmental Microbiology Laboratory (hereafter, the Laboratory) is currently analyzing drinking water for total coliforms and fecal coliforms (or *Escherichia coli*) using either Multiple Tube Fermentation (MTF) or Colilert (P/A). Furthermore source water is analyzed under the Long-term Enhanced Surface Water Treatment Rule using Colilert in the Quanti-tray format. In addition, although not performed routinely, the Laboratory has the capability to analyze drinking water using Membrane Filtration (MF). Furthermore, Heterotrophic Plate Counts (HPC), using the pour plate method, are regularly performed. The Laboratory wishes to maintain certification for all five methods: MTF, Colilert (P/A), Colilert (Quanti-tray), MF, and HPC.

The Laboratory has maintained an excellent record of PT sample analysis over the past three years. In 2007, 2008, and 2009 the Laboratory successfully analyzed PT sample sets using the MTF, Colilert (P/A), Colilert (Quanti-tray), MF, and HPC methods. All five methods were successfully performed each year.

The equipment and procedures employed in the bacteriological analyses of drinking water by this laboratory conform with the provisions of the *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition (2005, U.S. EPA), except as described in Sections C and D below.

B. Personnel:

The following personnel currently analyze drinking water or source water for total coliforms, fecal coliforms, (or *E.coli*), or the heterotrophic plate count.

Tom Ong	Microbiologist Supervisor
Mike Flesher	Microbiologist III
Tracey Goodson	Microbiologist III
Carole Moore	Microbiologist II
Christopher Smith	Microbiologist I

The assessor wishes to thank these individuals for their cooperation and assistance during the on-site evaluation. Tom Ong was especially helpful and generous with his time.

C. General Findings:

General Findings include specific incidences of non-conformance with the equipment and analytical procedures required by the *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition (2005, U.S. EPA), or laboratory procedures that, in the opinion of the assessor, jeopardize the generation of valid data. Note that all paragraph numbers and quotes are from Chapter V of the *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition (2005, U.S. EPA) unless otherwise indicated.

1. According to paragraph 5.1.6.3 the pH of commercially prepared media should be recorded for each lot. Colilert media is a commercially prepared dry sterile media sold in packets. One packet is used for each Colilert test. Currently the pH of Colilert media is not recorded by the Laboratory. Many drinking water laboratories have made an exception for Colilert media with regard to paragraph 5.1.6.3, perhaps because it was not a liquid prepared commercial media. However, paragraph 5.1.6.3 does apply to Colilert media, and thus, the pH will need to be checked for each lot and recorded.
2. According to paragraph 6.3.1 and 6.3.3, and the Federal Register (40 CFR 141.74(a)(1) footnote 2), samples collected in compliance with the SWTR must be held below 10°C during transit. Compliance with this requirement needs to be documented by recording sample temperature upon receipt at the Laboratory. The Laboratory currently analyzes HPC samples for ACS, but the samples are not iced during transit and are not checked for temperature upon receipt. If these samples are not compliance samples, that fact needs to be clearly established and documented.
3. In the previous edition (4th edition) of the SDWA *Manual for Certification of Laboratories Analyzing Drinking Water*, paragraph 5.1.6 stated that the “sample volume analyzed for total coliforms in drinking water must be 100 ml \pm 2.5 ml”. The Laboratory currently meets this requirement, using for comparison to test volumes, a dedicated vessel with volumes of 97.5 ml and 102.5 ml clearly marked. The current edition (5th edition) of the SDWA Manual, however, states in paragraph 5.1.5 that the “sample volume analyzed for total coliforms in drinking water must be 100ml.” Note that no \pm tolerance is indicated. The Federal Register, 40 CFR 141.21(f)(1), similarly states that the standard sample volume required for total coliform analysis, regardless of analytical method used, is 100ml.” The old acceptance limits (\pm 2.5 ml) are no longer applicable and consequently the Laboratory, henceforth, must make every attempt to measure and analyze exactly 100ml of sample. However, acknowledging that volume measurements by nature involve some error, the final sample volume may range from 100 ml to 102.5 ml. The Laboratory may use as a guide a new test vessel with the volumes of 100 ml and 102.5 ml clearly marked. Accordingly, samples with less than 100 ml must be rejected as having insufficient volume.

D. Recommendations:

The following remarks are offered as suggestions to help improve the quality and integrity of the data the Laboratory generates. Note that all paragraph numbers and quotes are from Chapter V of the *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition (2005, U.S. EPA) unless otherwise indicated.

1. The Laboratory's "Water Bacteriological Report" was revised in August, 2008, and continues to document considerable information about both sample collection and sample analysis. When reporting to the Environmental Engineering Section (EES) of the Office of Environmental Health Services this report is one of two sent. The other is an electronic reporting database known as the Safe Water Electronic Entry Tool or SWEET sent to the EED via the internet. Unfortunately, the latter reporting system does not report all the information contained in the Water Bacteriological Report. Of particular concern, are those instances where exceedance of holding time results in the following qualification on the paper Water Bacteriological Report: "Not valid for SDWA compliance reporting". This qualifying flag is not included in the electronic report. It is the assessor's understanding that the EES only reviews the electronic report and not the paper report, which means the qualification indicated on the latter is never actually communicated to the EES. Therefore, it is strongly suggested that such a critical data qualification be recorded in the SWEET system. Furthermore, based on conversations with Laboratory personnel, it is clear that the database has some predictable instabilities or glitches. Regular updates and improvement of SWEET by state IT personnel may be necessary and is strongly recommended.
2. Both paragraph 6.3.1 and the Federal Register (40 CFR 141.21(f)(3) footnote 2), in regard to the collection of drinking water samples from distribution systems, state, "Systems are encouraged but not required to hold samples below 10°C during transit." Accordingly, it is recommended that distribution system samples be held below 10°C during transit and that this condition be documented through the use of a temperature blank, the temperature of which would be determined upon arrival at the Laboratory and recorded.
3. Although the Water Bacteriological Report (WBR), which serves as both a sample collection form and a reporting form, contains a box to check if the sample is a compliance sample, use of the box was irregular and was often checked for what was clearly a non-compliance sample. For example, many of these sample collection forms were marked both "pool" and "compliance (SDWA)." Therefore, it appears that some sanitarians or other sample collectors do not really know what is or is not a compliance sample. A check next to "compliance (SDWA)" therefore did not necessarily mean that the sample was a compliance sample. Identification of a true compliance sample could only be done by noting a combination of pieces of information, such as the PWS number (beginning with 330 or 99), "Operator" indicated as title of collector, and "compliance (SDWA)" checked. A number of inaccurate or incomplete WBR forms were found. It is recommended that sample collectors

be better trained in how to accurately complete the form, and that they be instructed to check all boxes on the form that apply to the sample, so that the most complete record of sample collection is generated.

4. According to paragraph 8.4 analytical records should include the results of the analyses; however, the Laboratory, when it records the results of analyses on sheets kept in three-ring binders, only records the positive test results. Negative results are actually not recorded at all. The space available is left blank. Although Laboratory personnel all understand what the blank space means, the practice is contrary to common convention, contrary to paragraph 8.4, and results in an incomplete record of sample analysis. The problem could be easily corrected by embedding a “-“ as a default result in the space where results will be recorded. If the actual result is negative, the “-“ is already there to indicate that. If the result is positive, only a vertical line need be added to the “-“ in order to create “+”.
5. The SOPs for the methods performed need to be reviewed and updated. The HPC SOP is dated 1998, the MTF and MF SOPs 2000, and the Colilert P/A and Quantitray SOPs, 2006. The SOP for the Colilert P/A test, for instance, describes QC for the Colilert media that is not correct nor is it the current practice. All performance checks of the Colilert media need to be done with 100mL of sterile water and an entire media packet used per test vessel.
6. According to paragraph 3.15.4, “sufficient sodium thiosulfate must be added to a sample bottle before sterilization to neutralize any residual chlorine in the water sample.” The Laboratory currently uses sample bottles containing sodium thiosulfate and is also transitioning to commercially available (Idexx) pre-sterilized sample bottles containing sodium thiosulfate in powder form. In accordance with paragraph 3.15.4, the Laboratory should consider ways to confirm that the sodium thiosulfate contained in whichever sample bottle used is “sufficient” to neutralize the residual chlorine present in the water sample. One suggestion is to routinely check (using a check box on the Water Bacteriological Report) that the residual chlorine recorded on the report form by the sample collector is a residual concentration that can be neutralized by the amount of sodium thiosulfate known to be in the sample bottle. According to Idexx the pre-sterilized containers with sodium thiosulfate contain 10-35mg of sodium thiosulfate which will neutralize a minimum of 10 ppm residual chlorine. Laboratory staff could simply check the report form to be sure the residual chlorine recorded is less than or equal to 10 ppm and then check a box on the form documenting that this procedure had been completed. Alternatively, it is suggested the Laboratory use commercially available potassium iodide strips to test a small aliquot of the sample, transferred to a watch glass, for the presence of residual chlorine. If present the strip will change color indicating that the sodium thiosulfate had not been sufficient to neutralize all the residual chlorine in the water sample. If the sodium thiosulfate had been sufficient, no residual chlorine would remain and the color change would not occur. Whatever means of performing this check is decided upon, it should be described in method SOPs or in the Quality Assurance Manual.

E. General Comments:

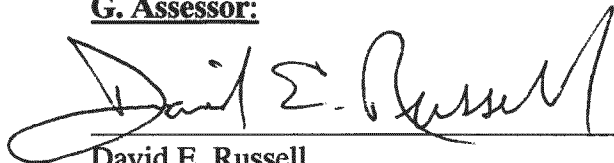
1. The Laboratory's "Water Bacteriological Report" was revised again in August, 2008, and continues to document considerable information about sample collection and analysis. One of the most commendable features is the extensive list of reasons for sample rejection. When a sample is rejected, the reason for rejection is clearly indicated. As in prior on-sites, the updated form is a good example of the Laboratory's commitment to continuous improvement.
2. The Laboratory is also to be commended for the routine practice of rejecting samples (without analysis) for the reasons listed on the Water Bacteriological Report.
3. The Laboratory is to be further commended for the documentation of QC using well-designed MS Excel spreadsheet logs containing embedded formulas for routine calculations and embedded automatic evaluations of QC data. Noteworthy, is the record of annual thermometer calibrations in which a single page is devoted to each thermometer and thus the entire history of calibration for a thermometer is easily reviewed.

F. Certification Status (Recommended by the Certification Officer):

The Laboratory's management and staff are to be commended for their dedication to maintaining high standards in microbiological analysis and remaining committed to continual improvement. Based upon this on-site assessment and contingent upon submission of acceptable corrective actions to address the Findings listed above in Section C, the Assessor recommends the following SDWA certification status:

LEGEND**C – Certified****PC - Provisionally Certified****IC - Interim Certified****NC - Not Certified**

Analyte Name	On-Site Certification Status 9/19/06	On-Site Method	Method Description
Coliforms, Total (presence/absence)	C	SM9221B	Multiple Tube Fermentation
Coliforms, Total (presence/absence)	C	SM9223 COLILERT	Colilert (Presence/Absence)
Coliforms, Total (presence/absence)	C	SM9222B	Membrane Filtration
Coliforms, Fecal (presence/absence)	C	SM9221B(E)	LTB => EC Broth
Coliforms, Fecal (presence/absence)	C	SM9222B	M-Endo Medium => EC Broth
Coliforms, E.coli (presence/absence)	C	SM9223 COLILERT	Colilert (Presence/Absence)
Escherichia coli (E. coli) (enumeration)	C	SM9223 COLILERTQT	Colilert Quanti-tray
Heterotrophic plate count (HPC) bacteria (enumeration)	C	SM 9215 B	HPC by Pour Plate

G. Assessor:

10/21/09

David E. Russell
Microbiological Assessor

